

§ 152.110

40 CFR Ch. I (7–1–13 Edition)

If an applicant for amended registration submits only that portion of the labeling proposed for amendment, the Agency may review the entire label, as revised by the proposed changes, in deciding whether to approve the amendment. The Agency will not approve final printed labeling, but will selectively review it for compliance.

§ 152.110 Time for agency review.

The Agency will complete its review of applications as expeditiously as possible. Applications subject to specific timeframes under the fee schedule established by FIFRA section 33 will be reviewed within the timeframes established for the application or action type.

[73 FR 75595, Dec. 12, 2008]

§ 152.111 Choice of standards for review of applications.

The Agency has discretion to review applications under either the unconditional registration criteria of FIFRA sec. 3(c)(5) or the conditional registration criteria of FIFRA sec. 3(c)(7). The type of review chosen depends primarily on the extent to which the relevant data base has been reviewed for completeness and scientific validity. EPA conducts data reviews needed to support unconditional registrations on a chemical-by-chemical basis, according to an established priority list. Except for applications for registration of a new active ingredient or in special cases where it finds immediate review to be warranted, the Agency will not commence a complete review of the existing data base on a given chemical in response to receipt of an application for registration. Instead the Agency will review the application using the criteria for conditional registration in FIFRA sec. 3(c)(7) (A) and (B).

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

(a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part;

(b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);

(c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5) with respect to the pesticide product which is the subject of the application;

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted for the product by part 158 or part 161 of this chapter, as applicable.

(e) The Agency has determined that the product will perform its intended function without unreasonable adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCa sec. 408, and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCa sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

[53 FR 15980, May 4, 1988, as amended at 72 FR 61028, Oct. 26, 2007; 73 FR 75595, Dec. 12, 2008]